Interim Licensing Report

Centre name:	Edinburgh Assisted Conception Unit
Centre number:	0201
Date licence issued:	01 March 2009
Licence expiry date:	28 February 2014
Additional conditions applied to this licence	None
Date of inspection:	12 September 2012
Inspectors:	Andrew Leonard (Lead); Susan Jolliffe
Executive Licensing Panel:	16 November 2012

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence. The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences at the centre and the recent progress in reducing the multiple pregnancy rate at the centre.

The Executive Licensing Panel (ELP) is asked to note that the report found no critical or major non-compliances but recommendations were made to address four 'other' areas of non-compliance or poor practice.

Since the inspection, the Person Responsible (PR) has confirmed and/or provided evidence that two of these recommendations have been fully implemented, these being:

1) The PR should ensure that the tubes are appropriately labelled and witnessed during egg collection, or that the current practice of not labelling or witnessing them is risk assessed and risk control measures are documented.
2) The PR must reassure himself that the reimbursements provided to donors by third party donor sperm procuring agents are compliant with General Direction 0001.

The PR has also described on-going actions to fully implement the remaining two recommendations within the timeframes detailed in this report, these being:

3) The PR must evaluate the ability of all third parties to meet the required standards.
4) The PR must ensure that licenced treatment data that the HFEA is required to hold on its register is submitted within the times stipulated.

Information about the centre

The Edinburgh Assisted Conception Unit (centre 0201) is also known as Edinburgh Fertility and Reproductive Endocrinology Centre (EFREC) and is located at the Royal Infirmary of Edinburgh. The centre has held a licence with the HFEA since 1992 and since 2002 at its current premises. The centre provides a full range of fertility services including embryo testing.

In the 12 months to 31 July 2012, the centre provided 629 cycles of treatment, which was comparable to the activity in the previous 12 months. In relation to activity levels, this is a medium sized treatment and storage centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of centres' ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending April 2012 show the centre's clinical pregnancy rates for IVF and ICSI are in line with national averages.

In 2011, the centre reported 11 cycles of partner intrauterine insemination with no pregnancies.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between April 2010 and March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 21%. This represented performance that was not likely to be statistically different from the 20% live birth rate target.

Between 1 April 2011 and 31 July 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This represented performance that was not likely to be statistically different from the 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target. The PR informed the inspection team verbally that the local commissioning groups now require single embryo transfer (SET) in all patients less than 40 years of age unless there are confounding medical issues or embryo quality is

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

low. This has meant that approximately 70% of patients now have an elective SET. The PR also discussed future plans to further optimise the multiple births minimisation strategy.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; thawing of gametes; preparation for embryo transfer. All of the procedures observed were manually witnessed and this was documented in accordance with HFEA requirements, with one exception discussed below. The inspection team noted the clear verbalisation of identifiers during witnessing at the centre and that staff were well briefed regarding witnessing procedures.

The inspection team was able to review witnessing documentation in the records of ten patients and concluded that all witnessing checks are effectively documented.

The tubes used during egg collection to transfer follicular fluid containing oocytes to the laboratory are not labeled with patient identifiers, so the transfer of follicular fluid from those tubes to dishes for microscopic observation cannot be witnessed. This leads to a risk that the eggs from one patient could be mixed up with those of another patient, if unmarked tubes containing eggs from the first patient were to be inadvertantly left in the procedure room or laboratory critical work area when a second egg collection commences. Observations and discussions on inspection indicated the laboratory staff were concerned that the time delay associated with labelling tubes and witnessing tube to dish transfers during egg collection, could be harmful to gametes because it delayed them being placed in the controlled environment of an incubator. Thus witnessing of this step was not performed. Instead the eggs of only one patient are present within the procedure room and the laboratory critical work area used for egg collection at any time. Furthermore, nursing and laboratory staff thoroughly clean the procedure room and laboratory critical work area after each egg collection, ensuring that the hot blocks are clear of tubes and all tubes are disposed of. Thus the risk of an unlabeled tube containing eggs from one egg collection being left to contaminate the next egg collection tube set is controlled and negligible. (Recommendation 1).

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 10 patients were reviewed in the course of the inspection. The consents were completed appropriately and reported to the HFEA accurately in all of the records reviewed.

Consent: To the storage of cryopreserved material

A review of the centre's electronic storage logs showed that all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period. The consented storage periods documented

in two patient records were checked against the storage periods recorded in the centre's storage logs. Both storage periods concurred between the two data sources.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to four patients who provided feedback on their experiences; we also observed interactions between centre staff and patients. A further 32 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 26 of the 32 respondents providing positive comments regarding the care they had received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- Has staff who are professional, caring, friendly, supportive and helpful
- Gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- Maintains an effective system for responding to patient phone calls

Monitoring the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified two non-compliances:

- The PR has no evidence that the reimbursements provided to donors by third party donor sperm procuring agents are compliant with regulatory requirements (see Recommendation 2).
- The centre has not evaluated the ability of all third parties to meet the required standards (see Recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the interim inspection on 20 July 2010, recommendations for improvement were made in relation to five major and seven 'other' areas of non-compliance. The PR subsequently provided evidence that all these recommendations were implemented within agreed timescales.

On-going monitoring of centre success rates

The centre's success rates are satisfactory and no HFEA risk tool alerts have needed to be issued to the centre regarding this matter.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

This centre has a good record of data submission and of compliance with related regulatory requirements. Nevertheless, there were a number of outstanding early outcome forms that needed to be submitted by the centre when the centre's data entry to the HFEA was assessed by the HFEA Registry team on 24 July 2012. Late submission and/or failure to submit Early Outcome forms can have an adverse impact on the mechanism by which the Authority monitors centre performance (see Recommendation 4).

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PRs statement
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PRs statement
None			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PRs statement
1) The tubes used during egg collection to transfer follicular fluid from the procedure room to the laboratory, are unlabeled and are not witnessed when the follicular fluid is decanted into dishes for microscopy, non-compliant with SLC T71 and T101.	The PR should ensure that the tubes and dishes used during egg collection are appropriately labelled and witnessed, or that the current practices are risk assessed and the SOPs state all actions to be taken to control any risk associated with the centre's current practices. Corrective actions should be implemented and advised to the HFEA by 12 December 2012.	A risk assessment has been carried out on our egg collection procedures and the risk of gamete misidentification has been found to be extremely low. Safe practice is predicated on clearance of all used products from the egg collection area prior to the next procedure starting and this is true whether the tubes are labelled or not. Our previous procedures included a significant clean up at the end of every case in which all sterile swabs, instruments, consumables, gowns etc etc were disposed of before the next patient was brought into the theatre. This is an essential pre-requisite for our infection control procedures and such an approach has been effective over a >20 year period with no identified problems in this area. However, in response to the comments of the HFEA inspector, we are always keen to improve our procedures further and therefore we have changed our paperwork such that there is now an actual sign off that all follicular aspirates have been examined and disposed of prior to the next case starting. We have included a double cross check at the level of the both the	The PR's response indicates that the centre's established practices significantly reduced the risks associated with this non-compliance. The further actions taken in response to this report have recognised any residual risks and mitigated them even further. The inspection team consider that the centre's changes in practices are likely to have reduced the risk of mix up to a negligible level. No further actions are required.

		laboratory and clinical teams. The laboratory SOP for oocyte collection already had directions for cleaning the workstation and disposing of used consumables after every egg collection, but further details have been added to include a specific instruction to embryologists to check the warming block in theatre as well as the laboratory workstation for any remaining tubes and a sign off at the beginning of every case that there are no residual tubes left in either block.	
2) The PR has no evidence that the reimbursements provided to donors by third party donor sperm procuring agents are compliant with General Direction 0001.	The PR must reassure himself that the reimbursements provided to donors by third party donor sperm procuring agents are compliant with General Direction 0001. This recommendation should be implemented by 12 December 2012	The supplier of donor sperm has been contacted regarding reimbursements to donors and they have provided a statement signed by the Medical Director and the Managing Director to confirm that they are compliant with HFEA regulations around the Import and Export of gametes and embryos (as outlined in General Directions Ref: 0006, Version 3). They state specifically that they meet the requirements set out in paragraph 1 a) b) c) e) f) and g) of these directions (which covers the reimbursement of money and benefits as set out in Directions 0001). We are therefore satisfied that the supplier is aware of the HFEA legislation covering this area and have recruited donors and reimbursed them in an approproriate manner.	The PR's response indicates that this recommendation has been complied with. No further actions are required.
3) The centre has not evaluated the ability of all third parties to meet	The PR must evaluate the ability of all third parties to meet the required standards	An audit of third parties will be carried out on an annual basis. We are developing such an audit at present.	The PR's response indicates that this recommendation is being

the required standards (SLC T112).	(SLC T112). This recommendation should be implemented by 12 March 2013.		implemented; completion will be reviewed through the on-going monitoring process. Further actions are required.
4) There were a number of outstanding Early Outcome forms that were late and needed to be submitted by the centre to the HFEA. Such late submission is non-compliant with General Direction 0005.	The PR must ensure that the outstanding Early Outcome forms are submitted and that, in future, licenced treatment data is submitted by the centre within the times stipulated in General Direction 0005. This recommendation should be immediately implemented.	Our Clerical officer was off on long term leave because of her illness. We have addressed this by having a part time Clerical Officer and our nursing staff are also involved submitting these forms. I have put this item for discussion at our Multidisciplinary meeting on a regular basis for the next few months to keep track of this.	The PR's response indicates that actions are being taken to implement this recommendation; these actions and their effects will be reviewed through the on-going monitoring process. Further actions are required.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

16 November 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0201 – (Edinburgh Assisted Conception Unit) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Matthew Watts, Regulatory Policy Manager David Moysen, Head of IT	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre had been licensed since 1992 and has been at its current premises since 2002. The centre provides a full range of fertility services including embryo testing.

2. The Panel noted that in the 12 months to 31 July 2012, the centre provided 629 cycles of treatment, which was comparable to the activity in the previous 12 months. In relation to activity levels this is a medium sized centre.

3. The Panel noted that, according to outcome data held on the HFEA Register for the year ending April 2012, the centre's clinical pregnancy rates for IVF and ICSI are in line with national averages.

4. The Panel noted that, at the time of the inspection, the Inspectorate identified four other areas of non-compliance.

5. The Panel noted that, since the inspection, the Person Responsible (PR) has implemented two of the recommendations made by the Inspectorate, and provided a commitment to fully address the other two areas of non-compliance identified within the prescribed timescales.

6. The Panel noted that the Inspectorate recommended that the centre's licence continue without additional conditions.

Decision

7. The Panel noted that the centre had implemented all recommendations from the previous inspection.

8. The Panel agreed with the Inspectorate's recommendations made in the report, including the on-going monitoring of auditing third parties and submitting data to the HFEA. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed:  Date: 27/11/12

Juliet Tizzard (Chair)